K022110

SEP 12 2002

EXHIBIT 17

510(k) SUMMARY

1. **Submitter**

Kawasumi laboratories, Inc.
3-28-15 Minami-Ohi
Shinagawa-Ku, Tokyo 140 Japan
Phone: 81-3-376-1151
Fax: 81-3-376-3235
Contact: Mr. S. Suwa

Authorized Contact

Kawasumi Laboratories America, Inc.
5905 C Hampton Oaks Parkway
Tampa, Fl 33610
Phone: 813-630-5554
Fax: 813-630-5033
Contact: Mr. Jack Pavlo

2. **Name of Device**: Antineedle Stick Protector for Use with Port Access Infusion Sets

   Common Name: Needle stick protector

3. **Predicate Device**: Portex Point-Lok Sharps Safety Device

4. **Description of the Device**: The Antineedle Stick Protector is a non-sterile, single use, active accessory device manufactured from polymeric material. The protector has two rectangular sides connected by a hinge. It is positioned over the port access wings, and is activated by snapping closed the hinged sides that will enclose and shield the port access infusion set needle within the protector.

5. **Intended Use**: The Antineedle Stick Protector is a non-sterile, single use accessory device intended to minimize accidental needle stick injuries when used an an active safety device to shield port access needles.

6. **Technological Characteristics**: The Antineedle Stick Protector is shaped differently than the predicate device and is activated in a different manner to achieve the same result. That is, the Antineedle Stick Protector is folded over and closed around the entire needle as it is removed from the patient. Use of the predicate device requires that the needle first be removed from the patient, and then the tip of the needle subsequently will be pushed into the device. In both devices, the needle tip is protected inside the device after use.

7. **Performance Data**: Kawasumi Laboratories has conducted a successful simulated use study to determine the acceptability of this device for use to minimize accidental needlestick injuries. Kawasumi Laboratories believes the successful simulated use study shows the device is suitable for its intended use and is substantially equivalent to the predicate device.

8. **Conclusions**: The device is as safe as the predicate device and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2002

Mr. Jack Pavlo
Manager, Technical Affairs
Kawasumi Laboratories, Incorporated
1800 Massachusetts Avenue N. W. Suite 200
Washington, D.C. 20036

Re: K022110
Trade/Device Name: Antineedle Stick Protector for use Port Access Infusion Sets
Regulation Number: 880.5570 and 880.5965
Regulation Name: Hypodermic Single Lumen Needle and Subcutaneous Implanted Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: FMI and LJT
Dated: June 27, 2002
Received: June 28, 2002

Dear Ms. Pavlo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022110

EXHIBIT 15

510(k) NUMBER (IF KNOWN): _____

DEVICE NAME: **Antineedle Stick Protector for use with Port Access Infusion Sets**

INDICATIONS FOR USE:

The Antineedle Stick Protector is a non-sterile, single use accessory device intended to minimize accidental needle stick injuries when used as an active safety device to shield port access needles.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use_ (Optional Format 1-

Patricia Cuccinotta
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K022110